

LIBELED: 2-13-64, N. Dist. Calif.

CHARGE: 403(f)—while held for sale, the information required to appear on the labels of the articles (except the gumbo file) under 403(e) (2), 403(i) (2), and 403(k), namely, an accurate statement of the quantity of contents, the common or usual name of each ingredient, and the declaration of artificial flavoring and coloring, was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

403(i) (2)—while held for sale, the gumbo file was fabricated from two or more ingredients and its label failed to bear the common or usual name of each such ingredient.

DISPOSITION: 4-17-64. Default—destruction.

SUGAR AND SIRUP

29728. Dextra Sugar (2 seizure actions). (F.D.C. Nos. 46745, 46746. S. Nos. 107 T, 54-804 T.)

QUANTITY: 119 cases, each containing 12 48-oz. bags, and 449 cases, each containing 12 3-lb. bags, at Tampa, Fla., and Jacksonville, Fla.

SHIPPED: 7-21-61, from Ottawa, Ohio, by Dextra Corp.

LABEL IN PART: (Case) "Dextra Fortified Sugar * * * Dextra Corporation, Ottawa, Ohio," and (bag) "New Dextra Brand Fortified Cane Sugar Fortified with Vitamins and Minerals White-Granulated * * * (4.1 Calories Per Gram) * * * Manufactured and Distributed in Florida by The Sugarlogics Southern Corporation, Delray Beach Florida."

RESULTS OF INVESTIGATION: Examination showed that the article consisted of over 98 percent sucrose.

LIBELED: 12-14-61, S. Dist. Fla.; libel amended 11-30-62.

CHARGE: 403(a)—when shipped, the name of the article was false and misleading, since it suggested and implied that the article was dextrose; 403(a)—the label contained false and misleading representations that the nutritional content of diets generally was significantly improved by use of the article; that the article in the ordinary diet was significantly more nutritious than any other sugar; that the article was of significant value because it restored vitamins and minerals lost in the refinement of cane juice; that all of the vitamins and minerals in the article were present in nutritionally significant amounts for special dietary use; and that the article was manufactured in Florida by the Sugarlogics Southern Corp., Delray Beach, Fla.; 403(a)—the label statement "4.1 calories per gram" was misleading since the specified calorie content of a gram of the article would not be understood by consumers generally, and the statements "Total Sugars (Carbohydrate) not less than 94%" and "Non-sugar solids not more than 6%" were misleading as applied to a product containing over 98 percent sucrose; 403(a)—the label when read in its entirety and through the use of such statements as "New * * * Fortified * * * Sugar," and "Fortified with Vitamins and Minerals," among others, represented, suggested, and implied that the American diet is significantly deficient in vitamins and minerals and that the article would supply the vitamins and minerals necessary to correct the implied deficiencies; and 403(i) (2)—the label of the article failed to bear the common or usual name of each ingredient, since it failed to bear the common or usual name of the vitamin and mineral compounds added to the article.

DISPOSITION: The articles were claimed by Sugarlogics Southern Corp. The two actions were consolidated and in January 1962, were transferred to the Miami Division of the Southern District of Florida.

The Government moved to strike all or portions of the claimant's answer on the grounds that the answer was ambiguous, argumentative and verbose, and contained redundant, immaterial, impertinent, and scandalous matter. A hearing was held on the motion on 4-23-62, and the court granted the motion in part, ordering some portions of the answer to be stricken.

On 5-23-62, the claimant filed a consolidated amended answer and cross-libel. The Government moved to strike and a hearing was held on 7-16-62. The court denied the motion to strike the answer, and granted the motion to strike the cross-libel.

On 8-22-62, the Government filed interrogatories which were answered by the claimant.

The matter came on for trial before the court on 11-29-62, and 11-30-62. The Government moved to amend the libel which motion was granted as to the charge that the label represented that the American diet was significantly deficient in minerals and vitamins and that the article would supply that necessary to correct the deficiencies. The court denied the motion to amend to include the charge under 403(a) that the label bore false and misleading statements that the article was cane sugar.

Post trial depositions were taken of expert witnesses unavailable for the trial.

On 2-21-63, the court issued its Findings of Fact and Conclusions of Law together with the following opinion:

CHOATE, *District Judge*: "This proceeding involves the question whether claimant's product, consisting of sugar fortified with vitamins and minerals, is misbranded and in violation of Section 403 of the Federal Food, Drug, and Cosmetic Act. While a number of charges are asserted in the libels of information filed herein, the Government's principal challenge is on a novel basis—that the offering of a fortified sugar, truthfully labeled to disclose such fortification, is misleading 'per se' to consumers. At the outset it is important to note that despite the sweeping nature of the consumer deception which this product is charged to create, the Government at the trial presented no actual evidence that consumers were misled by the product. The Government has chosen to rest its case on opinion evidence of several nutritionists despite the fact that in a seizure proceeding the burden is upon the Government to prove the ground for forfeiture alleged in the libel . . . by a fair preponderance of the evidence.' See, e.g., *United States v. 46 Cases, More or Less, Etc.*, 204 F. Supp. 321, 322 (D. R.I. 1962). It is clear that the Government failed to meet its burden in this case.

"The Government's witnesses' testimony was largely directed to their views regarding the most preferable means of supplying vitamins and minerals to consumers, and whether the fortification of sugar complied with a Statement of General Policy on fortification issued by the Food and Nutrition Board of the National Research Council. Such testimony plainly is not pertinent here. Section 403 of the Federal Food, Drug and Cosmetic Act permits the seizure and condemnation of goods only if they are *misbranded*, and that plainly means only if the labeling of the product is *false or misleading*.

"Section 301 of the Act merely empowers the Food and Drug Administration to issue 'a reasonable definition and standard of identity' so that consumers who purchase it can obtain 'assurance that they will get what they reasonably expect to receive'. See *Federal Security Administrator v. Quaker Oats Co.*, 318 U.S. 218, 232 (1943). Such standards have no bearing on the sale of a single, unique food product such as Dextra Brand Fortified Sugar.

"The Government charges that 'mere mention' on the labels of Dextra Brand Fortified Sugar of the fact that the product is fortified and the listing of the vitamins and minerals contained therein could be construed by consumers to

suggest or imply that vague generality known as the 'American diet' is deficient in the supply of vitamins and minerals, and that use of this product would overcome this deficiency.

"The Government also challenges the product as inherently deceptive on the ground that the disclosures regarding fortification misrepresent the product's nutritional significance in comparison with ordinary sugar. However, the Government's witnesses did not dispute that this product is an effective carrier of the vitamins and minerals added to respondent product, and that ordinary sugar contains none of these nutrients, and is commonly referred to in nutritional literature by the derogatory term, 'empty calories'. Indeed, the Government's own witnesses appeared to concede that in comparison with ordinary sugar, the product in fact was *significantly* more nutritious.

"The sole basis of the Government's charges is that the added nutrients are of no value because they are already in adequate supply in the American diet. This is clearly an untenable basis for holding the product misbranded.

"It is clear that the true basis for the objection to the fortification of sugar is not that the vitamins and minerals added to the sugar are of no nutritional value, but rather, that the Food and Drug Administration does not regard sugar as a preferable vehicle for fortification, or for addition of vitamins where a deficiency exists. In short they quarrel over the vehicle.

"The basic flaw in the Government's case against the product is that it is seeking, under the guise of misbranding charges, to prohibit the sale of a food in the marketplace simply because it is not in sympathy with its use. But the Government's position is clearly untenable. The provisions of the Federal Food, Drug, and Cosmetic Act did not vest in the Food and Drug Administration or any other federal agency the power to determine what foods should be included in the American diet; this is the function of the marketplace. Under Section 403 of the Act, Congress expressly limited the Government's powers of seizure to those products which are falsely or deceptively labeled. As the Supreme Court aptly stated in rejecting a similar attempt to overreach the authority granted by the Federal Food, Drug, and Cosmetic Act:

In our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop. *United States v. 62 Cases, Etc.*, 340 U.S. 593, 600 (1951).

"The Court does not undertake to constitute itself an arbiter of nutritional problems involved in determining more or less desirable agents for vending vitamin and mineral supplements to the consumer. The Congress did not provide the necessity of such determination. Neither will the Court permit a federal agency to appoint itself such an arbiter under the guise of prosecuting an action under the Act in question. Plainly only Congress can or should regulate the use of vitamins and then only to prevent public injury."

The Government filed a notice of appeal, and the claimant moved for return of the article under seizure. The claimant's motion was granted on 5-8-63, by order of the court, except as to one case of sugar in each of the original actions.

The Government moved to stay the execution of the order, and on 8-12-63, the United States Court of Appeals for the Fifth Circuit granted the stay.

Oral argument on the appeal was heard on 5-6-64, and on 7-9-64, the court rendered the following opinion (334 F. 2d 238) :

Before TUTTLE, *Chief Judge*, WISDOM, *Circuit Judge*, and MCRAE, *District Judge*.

PER CURIAM: "This case on appeal presents a very narrow issue. Brought under Section 304 of the Federal Food and Cosmetic Act, 21 U.S.C.A. § 334, the litigation was commenced by a seizure of certain cases of Dextra Brand Sugar. The sugar was alleged to have been misbranded within the meaning of Section 403(a) of the Act, 21 U.S.C.A. § 343(a), in that its label contained statements which were false or misleading. Although the Government charged initially that a number of the claims made on the face of the plastic bags in which the sugar was packed were misleading, these have all been abandoned

on appeal, except the statement, 'Almost any diet can be nutritionally improved by the use of DEXTRA Fortified Cane Sugar in place of sweetening agents containing only "empty" calories—calories unaccompanied by nutrients.'

"The Government based its entire case here on the proposition that proof below showed that the average American diet is adequate without the need to be 'nutritionally improved.' Therefore, it is argued, it is false to say that 'almost any [person's] diet can be nutritionally improved by the use of' dextra fortified cane sugar or anything else. The appeal also complains that the trial court erred in admitting certain evidence in the nature of studies and articles which were offered without an opportunity for cross-examination of the authors of the articles, and the Government also complained of the introduction into evidence of subsequent statements placed on packages later adopted by the owner of the seized product and proof that other products on the American market contained somewhat similar statements.

"In light of the fact that any purchaser of food products could elect to maintain his present 'average' diet with sufficient nutrients in it, or, if he wished, change to a different diet and substitute dextra fortified cane sugar for some other item, we conclude that the trial court was not in error in finding as a fact that the challenged statement was not false and misleading.

"We conclude that the alleged errors with respect to the admission of evidence are insubstantial and do not bear upon the correctness of the finding of fact which was dispositive of the case.

"The judgment of the trial court is, therefore,

AFFIRMED."

29729. Sorghum sirup. (F.D.C. No. 49819. S. Nos. 33-410/11 A.)

QUANTITY: 96 cases, each containing 12 cans, and 12 cases, each containing 24 cans, at Fayetteville, Tenn.

SHIPPED: Between 9-28-63 and 10-17-63, from Fayette, Ala., by B. E. Cobb.

LABEL IN PART: (Can) "Cobb's—Country Sorghum—Guaranteed Good No Additives—Net Wt. 3 Pt., 4 Fluid Oz. or [12 Case Lot "Net Contents 12 Fluid Oz."] B. E. Cobb * * * Fayette, Ala."

RESULTS OF INVESTIGATION: Examination showed that the article was approximately (96-case lot) 6.81 percent, and (12-case lot) 12.67 percent, short volume.

LIBELED: 3-9-64, E. Dist. Tenn.

CHARGE: 403(e) (2)—when shipped, the article failed to bear a label containing an accurate statement of quantity of contents since the label statement "Net Wt. 3 Pt. 4 Fluid Oz." [or 12-case lot "Net Contents 12 Fluid Oz."] was inaccurate.

DISPOSITION: 7-31-64. Consent—claimed by B. E. Cobb for relabeling.

29730. Sorghum sirup. (F.D.C. No. 50293. S. No. 59-240 A.)

QUANTITY: 128 4½-lb. cans at Overland Park, Kans.

SHIPPED: 11-29-63, from Kansas City, Mo., by Glen Broyles.

LABEL IN PART: (Can) "Country Sorghum * * * Made From Cane Juice Made For Glen Broyles, Distr. * * * Kansas City 18, Mo."

LIBELED: 6-17-64, Dist. Kans.

CHARGE: 402(b) (2)—when shipped, a mixture of sorghum and a sugar sirup had been substituted in whole or in part for sorghum sirup; and 403(a)—the label statement "Sorghum" was false and misleading as applied to a product consisting of a mixture of sorghum with a sugar sirup.

DISPOSITION: 9-21-64. Default—delivered to a Government institution.

29731. Malt-flavored sirups. (F.D.C. No. 49670. S. Nos. 78-326/28 X.)